Application No PCT/IE2004/000140

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 C07K14/235 A61K39/00 A61K39/10

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

 $\frac{\text{Minimum documentation searched (classification system followed by classification symbols)}{IPC~7~C07K~A61K}$

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, BIOSIS, PAJ, WPI Data, Sequence Search

C. DOCUMENTS CONSIDERED TO BE RELEVANT A the relevant passages Relevant to claim No.						
	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.				
Category °	Citation of document,					
Х	WO 93/21324 A (INSTITUT PASTEUR) 28 October 1993 (1993-10-28)	1,2, 12-24, 29-37, 65,66, 68, 76-88, 93-101				
	the whole document					
X	US 5 183 745 A (DANCHIN ET AL) 2 February 1993 (1993-02-02)	1,2, 12-24, 29-37, 65,66, 68, 76-88, 93-101				
	the whole document					
Patent (amily members are listed in annex.						

X Further documents are listed in the continuation of box C.	X Patent family members are listed in annex.
"A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed Date of the actual completion of the international search	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "&" document member of the same patent tamily Date of mailing of the international search report
10 February 2005	
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Hix, R

Internation Application No
PCT/IE2004/000140

	ation) DOCUMENTS CONSIDERED TO BE RELEVANT	Relevant to daim No.
Category °	Citation of document, with indication, where appropriate, of the relevant passages	nadvani io daini no.
X	EP 1 188 446 A (INSTITUT PASTEUR; CENTRE NATIONAL DE LA RECHERCHE SCIENTIFIQUE) 20 March 2002 (2002-03-20)	1,2, 12-24, 29-37, 65,66, 68, 76-88, 93-101
	page 6, column 2, paragraph 72 - paragraph 76	
X	COOTE J G ET AL: "The immunomodulatory and protective activities of adenylate cyclase toxin of Bordetella pertussis" ABSTRACTS OF THE GENERAL MEETING OF THE AMERICAN SOCIETY FOR MICROBIOLOGY, vol. 101, 2001, page 340, XP008042510 & 101ST GENERAL MEETING OF THE AMERICAN SOCIETY FOR MICROBIOLOGY; ORLANDO, FL, USA; MAY 20-24, 2001 ISSN: 1060-2011 the whole document	1,2
A	GENTILE F ET AL: "INVASIVE ADENYLYL CYCLASE OF BORDETELLA-PERTUSSIS PHYSICAL CATALYTIC AND TOXIC PROPERTIES" JOURNAL OF BIOLOGICAL CHEMISTRY, vol. 265, no. 18, 1990, pages 10686-10692, XP002316565 ISSN: 0021-9258 the whole document	
P,X	ROSS PADRAIG J ET AL: "Adenylate cyclase toxin from Bordetella pertussis synergizes with lipopolysaccharide to promote innate interleukin-10 production and enhances the induction of Th2 and regulatory T cells." INFECTION AND IMMUNITY, vol. 72, no. 3, March 2004 (2004-03), pages 1568-1579, XP002316566 ISSN: 0019-9567 the whole document	1,2

Form PCT/ISA/210 (continuation of second sheet) (January 2004)

Interior nal application No. PCT/1E2004/000140

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)					
This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:					
1. X Claims Nos.: 3, 5-11, 25-28, 38-64, 67, 69-75, 89-92 because they relate to subject matter not required to be searched by this Authority, namely:					
Although claims 1 to 37 and 65 to 101 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.					
2. Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:					
3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).					
Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)					
This International Searching Authority found multiple inventions in this international application, as follows:					
see additional sheet					
1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.					
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.					
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:					
No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: 1, 2, 65, 66 (completely); 4, 12-24, 29-37, 68, 76-88, 93-101 (partially)					
Remark on Protest The additional search fees were accompanied by the applicant's protest. No protest accompanied the payment of additional search fees.					

Form PCT/ISA/210 (continuation of first sheet (2)) (January 2004)

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1 and 2, 65, 66 (completely), claims 4, 12 to 24, 29 to 37, 68, 76 to 88, 93 to 101 (partially)

Use of an agent comprising adenylate cyclase toxin (CyaA) or derivative or mutant or fragment or variant or peptide thereof for the treatment and/or prophylaxis of an inflammatory and/or immune-mediated disorder, method of treatment and/or prophylaxis of an inflammatory and/or immune-mediated disorder comprising the step of administering an agent comprising CyaA or derivative or mutant or fragment or variant or peptide thereof.

2. claims: 3, 67 (completely), claims 4, 12 to 24, 29 to 37, 68, 76 to 88, 93 to 101 (partially)

Use of an agent comprising adenylate cyclase toxin (CyaA) or derivative or mutant or fragment or variant or peptide thereof for the treatment and/or prophylaxis of an autoimmune disease, method of treatment and/or prophylaxis of an autoimmune disease comprising the step of administering an agent comprising CyaA or derivative or mutant or fragment or variant or peptide thereof.

3. claims: 5 to 11, 25 to 28, 38 to 45, 47 to 55, 69 to 75, 89 to 92 (completely), claims 12 to 24, 29 to 37, 76 to 88, 93 to 101 (partially)

Use of an agent comprising adenylate cyclase toxin (CyaA) or derivative or mutant or fragment or variant or peptide thereof for the treatment and/or prophylaxis of an autoimmune disease, wherein the CyaA is combined with self or foreign antigens. A product comprising CyaA or derivative or mutant or fragment or variant or peptidein combination with a self or foreign antigen, pharmaceutical composition comprising CyaA; as adjuvant for immunization with a self or foreign antigen or in combination with a self or foreign antigen, method of treatment and/or prophylaxis of an autoimmune disease comprising the step of administering an agent comprising CyaA combined with a self or foreign antigen mutant or fragment or variant or peptide thereof.

4. claim: 46 and 59 to 62

A pharmaceutical composition comprising CyaA or derivative or mutant or fragment or variant or peptide thereof and vaccine comprising said CyaA .

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

5. claims: 56 and 58, claims 29 and 93 (partially)

A pharmaceutical composition comprising non-acylated CyaA or derivative or mutant or fragment or variant or peptide thereof, and a recombinant non-acylated CyaA having immunomodulatory effects.

6. claim: 57

An immunomodulator comprising adenylate cyclase toxin (CyaA).

7. claim: 63

Antibodies to CyaA.

8. claim: 64

An amino acid sequence from any one or more of SEQ ID NO: 3 or 4.

Information on patent family memoers

Internation Application No PCT/1E2004/000140

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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